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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,801	05/30/2001	John W. Cherwonogrodzky	3929-3	5677

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EXAMINER

FORD, VANESSA L

ART UNIT PAPER NUMBER

1645

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16

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Office Action Summary</b></p>	<b>Application No.</b> 09/866,801	<b>Applicant(s)</b> CHERWONOGRODZKY, JOHN W	
	<b>Examiner</b> Vanessa L. Ford	<b>Art Unit</b> 1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 and 30-62 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 and 59-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-58 and 62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
       Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
       If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

**DETAILED ACTION**

1. This Office Action is responsive to Applicant's amendments and response filed May 23, 2003 and August 25, 2003. Claims 1-5, 8-10, 30, 42-45 and 53 have been amended and claims 54-62 were added in the amendment submitted May 23, 2003. Claims 54 and 56 have been amended and claims 13 -29 have been cancelled in response to the amendment submitted August 25, 2003. Claims 59-61 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being to a non-elected invention.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

***Priority***

3. The Examiner acknowledges that receipt of the priority Documents filed October 17, 2001.

***Rejection Withdrawn***

4. In view of Applicant's amendment and Response, the rejection of claims 30-35, 41 and 46 under 35 U.S.C. 102(b) , pages 4-6, paragraph 6 is withdrawn.

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***Rejections Maintained***

5. The rejection of claims 30-36, 40-41 and 45-46 and newly submitted claims 56-57 under 35 U.S.C. 102(b) as being anticipated by Pasarell et al is maintained for the reasons set forth on pages 3-4, paragraph 5 of the previous Office Action.

The rejection was on the grounds that that Pasarell et al teach concentrated culture filtrate antigens that were obtained from the genera *Alternaria*, *Bipolaris*, *Curvularia*, *Dactylaria*, *Drechslera*, *Embellisia*, *Exserohilum*, *Fusarium*, *Helminthosporium*, *Microsporum*, *Scolecobasidium* and *Scopulariopsis*. Pasarell et al teach that the culture antigens were incubated and aerated on a rotating shaker (p. 1655, 2<sup>nd</sup> column). Pasarell et al teach that the concentrated culture filtrate antigens was used to immunize two New Zealand White female rabbits. Pasarell et al teach that an emulsion of 1 ml of each control antigen and 1 ml of Freund incomplete adjuvant was injected intramuscularly into the New Zealand rabbits. *Alternaria*, *Dactylaria*, *Drechslera*, *Embellisia*, *Fusarium*, *Micosporum*, *Scolecobasisum* and *Scolecobasidium* and *Scopulariopsis* did not have common antigens when tested against the antisera. Antigens of *Helminthosporium* only reacted with its own sera and there were no cross-reactions with any other antigens tested (p. 1656, 1<sup>st</sup> column). Pasarell et al teach that antisera prepared from *E. rostratum* recognized antigens prepared from *E. holmii*. Pasarell et al teach that a similar result was observed with antisera prepare from *E. mcginnisii* and *E. longirostratum*. Pasarell et al that common antigens are shared between the genera of *Bipolaris* and *Curvularia* (p. 1656). The process limitation of the supernatant being prepared and used at 20°C is a matter of design choice. Although the reference appears to disclose the same cell culture supernatant claimed by the Applicants, the reference does not disclose the cell culture supernatant being prepared at the same temperature as the claimed process. However, the production of a cell culture supernatant by a particular process does not impart novelty or unobviousness to a cell culture supernatant when the same cell culture supernatant is taught in the prior art. This particularly true when properties of the cell culture supernatant are not changed by the process in an unexpected manner. See *In re Thorpe*, 227 USPQ 964 (CAFC 1985); *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983); *In re Brown*, 173 USPQ 685 (CCPA 1972). The fungal or yeast culture of Pasarell, et al appears to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's fungal or yeast culture supernatant with the fungal or yeast culture supernatant of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i.e., that the fungal or yeast culture supernatant of the prior art does not possess the same material

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structural and functional characteristics of the claimed fungal or yeast culture supernatant). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that Pasarell used an Amicon PM10 filter which discard anything in the filtrate that is less than 10,000 m.w. while retaining large proteins. Applicant urges that the presently claimed invention provides a fungal cell culture supernatant containing fungal or yeast components shedded to the supernatant during culturing. Applicant urges that the presently claimed invention defines a supernatant which retained all or substantially all of the components in the supernatant such as for example aflatoxins which have a molecular weight of for example less than 400 m.w. Applicant urges that antigens from several bacteria do not cause (cross?) react. Applicant urges that the reference teaches away from the claimed invention. Applicant urges that the cited reference fails to teach each and every aspect of the presently claimed invention.

Applicant's arguments filed May 23, 2003 have been fully considered but they are not persuasive. It is the Examiner's position that Applicant is arguing limitations that are not in the claims. The claims are drawn to a fungal or yeast cell supernatant as antigenic source for detecting level of antibodies from a sample test subject said fungal cell culture supernatant containing fungal components shed in to the supernatant during culturing; said antigenic source having a reduction of activity of less than 20% as measured by ELISA after treatment with protease in 0.25M TRIS buffer at pH 7.2. Pasarell et al teach concentrated culture filtrate antigens that were obtained from the

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genera *Alternaria*, *Bipolaris*, *Curvularia*, *Dactylaria*, *Drechslera*, *Embellisia*, *Exserohilum*, *Fusarium*, *Helminthosporium*, *Microsporum*, *Scolecobasidium* and *Scopulariopsis*. Pasarell et al teach that the culture antigens were incubated and aerated on a rotating shaker (p. 1655, 2<sup>nd</sup> column). There is no requirement in the claims that requires that the cell culture supernatant be filtered with a specific filter. Although the reference appears to disclose the same cell culture supernatant claimed by the Applicants, the reference does not disclose the cell culture supernatant being prepared at the same temperature as the claimed process. However, the production of a cell culture supernatant by a particular process does not impart novelty or unobviousness to a cell culture supernatant when the same cell culture supernatant is taught in the prior art. This particularly true when properties of the cell culture supernatant are not changed by the process in an unexpected manner. See *In re Thorpe*, 227 USPQ 964 (CAFC 1985); *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983); *In re Brown*, 173 USPQ 685 (CCPA 1972). It should be noted that the claims are drawn to a product (a cell culture supernatant) which would inherently possess all of the same characteristics as the claimed cell culture supernatant. Applicant has provided no side-by-side comparison to show that the fungal cell culture supernatant of the prior art differs from the claimed fungal cell culture supernatant.

In regards to Applicant's argument concerning cross-reactivity, Pasarell et al teach that antisera prepared from *E. rostratum* recognized antigens prepared from *E. holmii*. Pasarell et al teach that a similar result was observed with antisera prepared from *E. mcginnisii* and *E. longirostratum*. Pasarell et al that common antigens are shared

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between the genera of *Bipolaris* and *Curvularia* (p. 1656). Therefore, the teaching of Pasarell et al anticipate the claimed invention.

6. The rejection of claims 30-35, 37-39, 41 and 45-46 under 35 U.S.C. 102(b) as being anticipated by Takesako et al is maintained for the reasons set forth on pages 6-8, paragraph 7 of the previous Office Action.

The rejection was on the grounds that Takesako et al teach the preparation of fungal antigens (i.e. *Candida albicans*, *Cryptococcus neoformans* and *Aspergillus fumigatus*). Takesako et al teach that the fungal antigens were suspended in Potato-Dextrose medium and subject to shaking overnight (column 27, lines 3-6). Takesako et al teach that *Candida* serum exhibited cross reactivity to proteins derived from *Cryptococcus neoformans* and *Aspergillus* (column 38, lines 25-28). Takesako et al teach that *Aspergillus* serum showed cross-reactivity with *Cryptococcus* (column 38, lines 39-41). Takesako et al teach fungal antigen solutions that are mixed with equal volumes of incomplete Freund's adjuvant yield a water-in-oil vaccine preparation (column 28, lines 59-62). Limitations such as "the supernatant is prepared and used at 20°C" are viewed as a matter of design choice.

Since the Office does not have the facilities for examining and comparing applicant's fungal or yeast culture supernatant with the fungal or yeast culture supernatant of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i.e., that the fungal or yeast culture supernatant of the prior art does not possess the same material structural and functional characteristics of the claimed fungal or yeast culture supernatant). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant submit that the fungal antigen of Takesako et al appear to be proteins. Applicant urges that such protein would be damaged by proteinases to a great extent such that the presently claimed invention does not define the product of Takesako et al.

Applicant's arguments filed May 23, 2003 have been fully considered but they are not persuasive. It is the Examiner's position that Applicant is arguing limitations that are not in the claims. The claims are drawn to a fungal or yeast cell supernatant as

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antigenic source for detecting level of antibodies from a sample test subject said fungal cell culture supernatant containing fungal components shed in to the supernatant during culturing; said antigenic source having a reduction of activity of less than 20% as measured by ELISA after treatment with protease in 0.25M TRIS buffer at pH 7.2.

Takesako et al teach the preparation of fungal antigens (i.e. *Candida albicans*, *Cryptococcus neoformans* and *Aspergillus fumigatus*) and Takesako et al teach that *Candida* serum exhibited cross reactivity to proteins derived from *Cryptococcus neoformans* and *Aspergillus* (column 38, lines 25-28). Takesako et al further teach that *Aspergillus* serum showed cross-reactivity with *Cryptococcus* (column 38, lines 39-41). Although the reference appears to disclose the same cell culture supernatant claimed by the Applicants, the reference does not disclose the cell culture supernatant being prepared at the same temperature as the claimed process. However, the production of a cell culture supernatant by a particular process does not impart novelty or unobviousness to a cell culture supernatant when the same cell culture supernatant is taught in the prior art. This particularly true when properties of the cell culture supernatant are not changed by the process in an unexpected manner. See *In re Thorpe*, 227 USPQ 964 (CAFC 1985); *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983); *In re Brown*, 173 USPQ 685 (CCPA 1972). It should be noted that the claims are drawn to a product (a cell culture supernatant) which would inherently possess all of the same characteristics as the claimed cell culture supernatant. Applicant has provided no side-by-side comparison to show that the fungal cell culture supernatant of the prior art



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differs from the claimed fungal cell culture supernatant. Therefore, the teaching of Takesako et al anticipate the claimed invention.

7. The rejection of claims 30-36, 41-42, 44-51 and newly submitted claims 55-56, 58 and 62 under 35 U.S.C. 102(b) as being anticipated by van der Heide et al is maintained for the reasons set forth on pages 8-9, paragraph 8 of the previous Office Action.

The rejection was on the grounds that that van der Heide et al teach *Aspergillus fumigatus*, *Penicillium notatum*, *Alternaria alternata* and *Cladosporium herbarum* antigenic extracts (see the Abstract and page 593, 1<sup>st</sup> column). van der Heide et al teach that 3 rabbits were immunized (1 rabbit per fungus) with an antigen mixture in Freund's adjuvant (page 593). It would be inherent that the *Aspergillus* antigens would be effective in detecting aflatoxins since aflatoxins are obtained from microorganisms of the genera *Aspergillus*. Limitations such as "the supernatant is prepared and used at a temperature above freezing" and the supernatant is prepared and used at 20°C are viewed as limitation of design choice. The limitation of detecting level of antibodies from a sample test subject" is a limitation of intended use.

Since the Office does not have the facilities for examining and comparing applicant's fungal culture supernatant with the fungal culture supernatant of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i.e., that the fungal culture supernatant of the prior art does not possess the same material structural and functional characteristics of the claimed fungal culture supernatant). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that method of van der Heide et al teach the use of an H4P5 hollow fiber Amicon filtration. Applicant urges that the dialysate of van der Heide are frozen. Applicant urges that proteins are at most a minor component of the claimed invention as only a minor reduction in activity is found with proteinase digestion.

Applicant's arguments filed May 23, 2003 have been fully considered but they are not persuasive. It is the Examiner's position that Applicant is arguing limitations that

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are not in the claims. The claims are drawn to a fungal or yeast cell supernatant as antigenic source for detecting level of antibodies from a sample test subject said fungal cell culture supernatant containing fungal components shed in to the supernatant during culturing; said antigenic source having a reduction of activity of less than 20% as measured by ELISA after treatment with protease in 0.25M TRIS buffer at pH 7.2. van der Heide et al teach *Aspergillus fumigatus*, *Penicillium notatum*, *Alternaria alternata* and *Cladosporium herbarum* antigenic extracts. There is no requirement in the claims that requires that the cell culture supernatant be filtered with a specific filter. Although the reference appears to disclose the same cell culture supernatant claimed by the Applicants, the reference does not disclose the cell culture supernatant being prepared at the same temperature as the claimed process. However, the production of a cell culture supernatant by a particular process does not impart novelty or unobviousness to a cell culture supernatant when the same cell culture supernatant is taught in the prior art. This particularly true when properties of the cell culture supernatant are not changed by the process in an unexpected manner. See *In re Thorpe*, 227 USPQ 964 (CAFC 1985); *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983); *In re Brown*, 173 USPQ 685 (CCPA 1972). It should be noted that the claims are drawn to a product (a cell culture supernatant) which would inherently possess all of the same characteristics as the claimed cell culture supernatant. Applicant has provided no side-by-side comparison to show that the fungal cell culture supernatant of the prior art differs from the claimed fungal cell culture supernatant. Therefore, the teaching of van der Heide et al anticipate the claimed invention.

8. The rejection of claim 43 under 35 U.S.C. 102(b) as being anticipated by Pasarell et al is maintained for the reasons set forth on page 10, paragraph 9 of the previous Office Action.

The rejection was on the grounds that Pasarell et al teach concentrated culture filtrate antigens that were obtained from the genera *Bipolaris*. Pasarell teach that reference antisera was tested by a microimmudiffusion method against concentrated filtrates including *Bipolaris spp.* Pasarell et al teach that cross-reactivity was shown between isolates of the genera *Biopolaris* and *Curvularia*. Cross-reactivity was also seen among the different species of *Bipolaris*.

Since the Office does not have the facilities for examining and comparing applicant's fungal culture supernatant with the fungal culture supernatant of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i.e., that the fungal culture supernatant of the prior art does not possess the same material structural and functional characteristics of the claimed fungal culture supernatant). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that Pasarell used an Amicon PM10 filter which discard anything in the filtrate that is less than 10,000 m.w. while retaining large proteins. Applicant urges that the presently claimed invention provides a fungal cell culture supernatant containing fungal or yeast components shedded to the supernatant during culturing. Applicant urges that the presently claimed invention defines a supernatant which retained all or substantially all of the components in the supernatant such as for example aflatoxins which have a molecular weight of for example less than 400 m.w. Applicant urges that antigens from several bacteria do not cause (cross?) react. Applicant urges that the reference teaches away from the claimed invention. Applicant urges that the cited reference fails to teach each and every aspect of the presently claimed invention.

Applicant's arguments filed May 23, 2003 have been fully considered but they are not persuasive. It is the Examiner's position that Applicant is arguing limitations that are not in the claims. The claims are drawn to a fungal cell culture supernatant of *Biopolaris* as an antigenic source for detecting antibody levels from a sample test subject, said fungal cell culture supernatant containing fungal components shed into the supernatant during culturing said fungal culture. Pasarell et al teach concentrated culture filtrate antigens that were obtained from the genera *Alternaria*, *Bipolaris*, *Curvularia*, *Dactylaria*, *Drechslera*, *Embellisia*, *Exserohilum*, *Fusarium*, *Helminthosporium*, *Microsporum*, *Scolecobasidium* and *Scopulariopsis*. Pasarell et al teach that the culture antigens were incubated and aerated on a rotating shaker (p. 1655, 2<sup>nd</sup> column). There is no requirement in the claims that requires that the cell culture supernatant be filtered with a specific filter. Although the reference appears to disclose the same cell culture supernatant claimed by the Applicants, the reference does not disclose the cell culture supernatant being prepared at the same temperature as the claimed process. However, the production of a cell culture supernatant by a particular process does not impart novelty or unobviousness to a cell culture supernatant when the same cell culture supernatant is taught in the prior art. This particularly true when properties of the cell culture supernatant are not changed by the process in an unexpected manner. See *In re Thorpe*, 227 USPQ 964 (CAFC 1985); *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983); *In re Brown*, 173 USPQ 685 (CCPA 1972). It should be noted that the claims are drawn to a product (a cell culture supernatant) which would inherently possess all of the same characteristics as the

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claimed cell culture supernatant. Applicant has provided no side-by-side comparison to show that the fungal cell culture supernatant of the prior art differs from the claimed fungal cell culture supernatant.

In regards to Applicant's argument concerning cross-reactivity, Pasarell et al teach that antisera prepared from *E. rostratum* recognized antigens prepared from *E. holmii*. Pasarell et al teach that a similar result was observed with antisera prepared from *E. mcginnisii* and *E. longirostratum*. Pasarell et al that common antigens are shared between the genera of *Bipolaris* and *Curvularia* (p. 1656). Therefore, the teaching of Pasarell et al anticipate the claimed invention.

***New Ground of Rejection Necessitated by Amendment***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 54 is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 54 recites "under alkaline conditions". It is unclear as to what Applicant is referring? Clarification is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 54 is rejected under 35 U.S.C. 102(b) as anticipated by Malling et al (*Allergy, January 41(1):57-67*).

Claim 54 is drawn to a fungal cell culture supernatant of *Cladosporium* displaying false positive indication under alkaline conditions towards antibody detection in a serodiagnostic assay for fungal antibody said assay comprising reacting said fungal cell culture supernatant with sera from a test subject and determining the serum antibody level of test subject.

Malling et al teach the use *Cladosporium* in serodiagnostic assays in adult asthmatic patients (see the Abstract). Malling et al teach that *Cladosporium* displays false positive indication towards antibody detection in a serodiagnostic assay for fungal antibody (page 61).

Since the Office does not have the facilities for examining and comparing applicant's fungal culture supernatant with the fungal culture supernatant of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i.e., that the fungal culture

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supernatant of the prior art does not possess the same material structural and functional characteristics of the claimed fungal culture supernatant). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

### ***New Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 52 and 53 are rejected under 35 U.S.C. 102(b) as anticipated by Brewer et al (*Canadian Journal of Microbiology*, September 1978, 24(9), 1078-81).

Claims 52 and 53 are drawn to cell culture supernatants of *Chaetomium* as an antigenic source for detecting levels of antibodies specifically reacting thereto for test subject.

Brewer et al teach cell cultures of *Chaetomium* spp. Isolated from soil (see the Abstract and Materials and Methods Section). The *Chaetomium* spp. of Brewer et al would inherently have the same properties as the claimed cell culture supernatant of *Chaetomium*. The claim limitation “as an antigenic source for detecting levels of antibodies specifically reacting thereto for test subject” is being viewed as a limitation of intended use.

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Since the Office does not have the facilities for examining and comparing applicant's fungal culture supernatant with the fungal culture supernatant of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i.e., that the fungal culture supernatant of the prior art does not possess the same material structural and functional characteristics of the claimed fungal culture supernatant). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.


### ***Status of Claims***

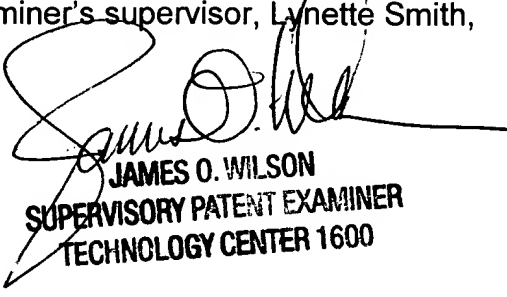
12. No claims are allowed.

13. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

  
Vanessa L. Ford  
Biotechnology Patent Examiner  
November 13, 2003

  
JAMES O. WILSON  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600